K061635

MSD BIPOLAR Forceps
510(k) Summary
June 2006

I. Company: **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

SEP - 5 2006

Contact: **Richard W. Treharne, PhD**
Vice President Regulatory Affairs

II. **Proprietary Trade Name: MSD BIPOLAR Forceps**

III. **Classification Name: Electrosurgical Cutting and Coagulation and Accessories**

IV. **Regulation Number: 878.4400**

Product Code: GEI

Class: Class II

V. **Product Description**

The MSD BIPOLAR Forceps are intended for use in general surgical procedures. The device is connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch.

VII **Indications**

The MSD BIPOLAR Forceps are designed to grasp, manipulate and coagulate selected tissue. It is to be connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar Forceps must only be used with bipolar coagulation current. The MSD BIPOLAR Forceps has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

VIII **Substantial Equivalence**

Documentation was provided which demonstrated the subject MSD BIPOLAR Forceps to be substantially equivalent to the CLARIS Non-Stick Bipolar Forceps previously cleared by the agency in K051429 (SE 07/29/05).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Medtronic Sofamor Danek
% Mr. Lee Grant
Supervisor, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K061635
Trade/Device Name: MSD Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 11, 2006
Received: August 15, 2006

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061635

Device Name: MSD Bipolar Forceps

Indications for Use:

The MSD BIPOLAR Forceps are designed to grasp, manipulate and coagulate selected tissue. It is to be connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar Forceps must only be used with bipolar coagulation current. The MSD BIPOLAR Forceps has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, R
and Neurological Devi

510(k) Number K061636